In the United States Court of Federal Claims

No. 15-085V
(Filed Under Seal: March 2, 2017)[1]
(Released for Publication: March 28, 2017)

**********	
MYKELLE JIVON D'TIOLE,	*
Petitioner,	* Vaccine Act, 42 U.S.C. §§ 300aa-1 *et seq.*; * Review of Special Master's Decision; * Off-Table Injury; Narcolepsy with Cataplexy
v.	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
Respondent.	*
**********	

Curtis R. Webb, Curtis R. Webb, Twin Falls, ID, for Petitioner.

Lara Ann Englund, US Dep't of Justice, Washington, DC, for Respondent.

ORDER AND OPINION

Damich, Senior Judge:

On December 28, 2016, Petitioner, Mykelle Jivon D'Tiole, filed a petition for review of the Special Master's Decision denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012), ("Vaccine Act").[2] Petitioner alleged that an influenza ("flu") vaccine administered on December 13, 2011, while he was a minor and without his parents' permission, caused him to develop narcolepsy with cataplexy. On November 28, 2016, Special Master Brian H. Corcoran denied compensation on the grounds that

[1] Vaccine Rule 18(b), contained in Appendix B of the Rules of the United States Court of Federal claims ("RCFC"), affords each party fourteen days to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

[2] Petitioner's parents originally filed this claim on his behalf while he was a minor, but as he is of majority status, he is now identified as the Petitioner.

Petitioner did not establish by preponderant evidence that the vaccine caused Petitioner's narcolepsy with cataplexy. *D'Tiole v. Sec'y of HHS*, No. 15-085V, 2016 U.S. Claims LEXIS 2003, at *81 (Fed. Cl. Nov. 28, 2016) (hereinafter "*D'Tiole*").

In his motion for review, Petitioner requested this Court to enter judgment in his favor, and argued that the Special Master improperly required the Petitioner to prove causation through epidemiologic evidence as well as a specific biologic mechanism. The Petitioner also claimed that the Special Master abused his discretion when he issued a decision without a hearing.

For the reasons set forth below, the Court finds that the Special Master's decision was not arbitrary or capricious, or otherwise not in accordance with law, as he properly weighed the evidence, nor did he abuse his discretion by declining to hold a hearing. Petitioner's motion for review is, therefore, **DENIED**.

I. Factual Background

On December 13, 2011, Petitioner went to his pediatrician for a well child visit. *D'Tiole*, at *2. At that time, Petitioner received FluMist [3], a live attenuated influenza vaccine ("LAIV"). *Id.* His parents did not consent for him to receive the vaccine, and were not made aware of this until the spring of 2014. *D'Tiole*, at * 8.

On February 1, 2012, Petitioner was taken for treatment to the John Muir Medical Center Emergency Department ("Emergency Department") after he had hurt his wrist falling while playing basketball. *D'Tiole*, at *2. He was diagnosed with a wrist fracture and underwent a closed reduction with percutaneous pinning under general anesthesia. *Id.*

On February 10, 2012, Petitioner saw his pediatrician for a follow-up examination of his wrist fracture. *D'Tiole*, at *2-3. Petitioner offered statements suggesting that his sleep-related symptoms began around this time. *D'Tiole*, at *3. His mother, Ms. Sevela DePlush, stated that she noticed Petitioner behaving "differently" and "began noticing him exhibiting severe

[3] As noted in *Agnew v. Sec'y of HHS,* No. 12-551V, 2016 WL 1612853, at *3 (Fed. Cl. Spec. Mstr. Mar. 30, 2016), FluMist is a cold-adapted vaccine received intranasally. It contains live, but attenuated (meaning reduced in virulence), strains of the wild flu virus. *See* FluMist Package Insert, filed on June 20, 2016, as Resp't's Ex. G (Resp't's Mot. for a Ruling on the Record), at 13-14. To achieve an immune response from the body's adaptive immune system, the viral strains contained in the vaccine replicate at a temperature consistent with that found in the nasal cavity, but not at the higher temperatures found elsewhere in the body. *Agnew*, 2016 WL 1612853, at *3. As a result, the flu strain can replicate sufficiently to produce the antibodies necessary to fight a wild infection, without itself replicating enough to cause infection if transmitted to others. *See* Resp't's Ex. G at 13 ("the attenuated vaccine virus replicates to induce protective immunity"). In this case, Petitioner received a trivalent version of the vaccine, meaning that it "contain[s] three vaccine virus strains which are thought most likely to cause disease outbreaks during influenza season." *National Vaccine Injury Compensation Program: Addition of Trivalent Influenza Vaccines to the Vaccine Injury Table*, 70 Fed. Reg. 19,092 (Apr. 12, 2005).

drowsiness" by February 2012, right after his surgery. *Id.* There are no medical records at this time, however, that refer to Petitioner's sleeping problems. *D'Tiole*, at *2-3.

Over a month later, on March 26, 2012, Petitioner saw his pediatrician again, complaining of ear pain and feeling tired all of the time. *D'Tiole*, at *3. The notes from this visit specifically state that he was falling asleep at 11 a.m. after waking at 6 a.m. *Id.* After this visit, Petitioner was prescribed antibiotics for his ear pain and was instructed to engage in better sleeping hygiene (*e.g.*, limiting television time before sleep). *D'Tiole*, at *3-4.

After a four month gap, on July 18, 2012, Petitioner was seen again by his pediatrician complaining that he had difficulties with his equilibrium and a "hard time focusing." *D'Tiole*, at *4. The medical notes include statements by Petitioner that he was playing videogames late into the night, sleeping until noon thereafter, and having trouble focusing – but the examiner also noted that he was not experiencing dizziness or balance problems. *Id.* His examiner assessed him with a dysfunctional sleep pattern and directed him to care for the condition in a similar manner to that recommended in March 2012. *Id.*

On September 6, 2012, Petitioner saw his pediatrician, complaining again about his lack of focus and constant sleepiness. *Id.* The medical note indicated that the Petitioner was still feeling tired and had trouble focusing. *D'Tiole*, at *5. The medical record also indicates that Petitioner was experiencing short "tremors" involving his eyelids drooping and his eyes wandering. *Id.* The impression to his examiner was possible seizure activity, and Petitioner was referred to a neurologist at Children's Hospital in Oakland, California ("Children's Hospital"). *Id.*

On October 5, 2012, Petitioner underwent an initial neurological evaluation at Children's Hospital, and received an electroencephalogram ("EEG"). *Id.* The results of the EEG were normal. *Id.* Petitioner was also seen by a specialist in the epilepsy department. *Id.* The medical diagnosis, based on the exam as well as the EEG results, indicated that Petitioner was not suffering from epilepsy. *Id.* The notes described Petitioner's continued dizzy spells and eye-fluttering episodes, and categorized them as "recently experienced." *Id.* Petitioner's sleep problems were also mentioned, but were not identified as persistent. *Id.* The notes also stated that Petitioner often slept late on weekends with poor sleep hygiene as the likely cause of such problems. *D'Tiole*, at *6.

On December 16, 2012, Petitioner was seen in the Emergency Department, where he reported "he had 2 or 3 episodes at home where he felt weak and could not stand up and had some shaking of his extremities." *Id.* The assessment section noted: "shaking episodes of uncertain cause," and a diagnosis of "altered consciousness." *Id.*

In August 2013, Petitioner was examined by Stanford Hospital's Sleep Medicine Clinic in Redwood City, California ("Clinic"). *Id.* The Clinic diagnosed him with "hypersomnia due to

medical condition classified elsewhere and narcolepsy[4] with cataplexy."[5] *D'Tiole*, at *7. Notes contained in the record from the August 2013 visit identify statements by Petitioner's mother that "everything seemed to start after [Petitioner] broke his wrist and required anesthesia." *Id.* The notes also recorded progression in his symptoms, with a more robust daytime sleepiness. *Id.* The medical examiner prescribed a trial of modafinil.[6] *Id.*

By 2014, Petitioner received further treatment for his symptoms, and narcolepsy with cataplexy was no longer merely suspected but confirmed as the proper diagnoses. *Id.* The confirmation was strengthened through tests (performed by the Clinic on January 15, 2014) revealing that Petitioner likely possessed the HLA allele[7] associated with narcolepsy.[8] *D'Tiole*, at *7-8. It was during treatment at the Clinic that Petitioner was confirmed to test positive for this specific HLA allele. *D'Tiole*, at *8.

II. Procedural History

Petitioner filed a petition for compensation under the Vaccine Act on January 27, 2015, claiming that the vaccine he received on December 13, 2011 caused him to develop narcolepsy with cataplexy.

On July 13, 2015, Respondent filed its Rule 4(c) Report asserting that Petitioner was not entitled to compensation because he could not carry the burden of proof under *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). After the Rule 4(c) Report was filed, the experts for each party submitted their reports. The Special Master then held a status conference. After a status conference, the Special Master proposed on February 16, 2016, that the Respondent move for a decision on the papers, as it was his assessment that it would be the most expeditious approach to resolving the case. On November 28, 2016 the Special Master's decision was

---

[4] Narcolepsy is defined as "recurrent, uncontrollable, brief episodes of sleep, often associated with . . . hallucinations, cataplexy, and sleep paralysis." *Dorland's Illustrated Medical Dictionary* 1232 (32nd ed. 2012) (hereinafter "*Dorland's*").

[5] Cataplexy is a condition characterized by abrupt attacks of muscular weakness and hypotonia triggered by an emotional stimulus such as mirth, anger, fear, or surprise. *Dorland's* at 303.

[6] Modafinil is a central nervous system stimulant, administered orally, used in the treatment of narcolepsy, obstructive sleep apnea, and sleep disorders associated with shift work. *Dorland's* at 1171.

[7] In layman's terms, an allele is a variant form of a gene that appears at a particular location on a particular chromosome. Regina Bailey, Allele – A Genetics Definition, About (Feb. 17, 2017), http://biology.about.com/od/geneticsglossary/g/alleles.htm. In this case, we are discussing a narcolepsy specific allele.

[8] The specific HLA allele associated with narcolepsy with cataplexy is the HLA class II DQB1*06:02, the same allele Petitioner has. *See generally* Mehdi Tafti, et al, *Narcolepsy-Associated HLA Class I Alleles Implicate Cell-Mediated Cytotoxicity*, 39(3) Sleep 581 (Mar. 1, 2016), found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4763366 ("Our findings provide a genetic basis for increased susceptibility to infectious factors or an immune cytotoxic mechanism in narcolepsy, potentially targeting hypocretin neurons.").

published. On December 19, 2016, Petitioner filed a Motion for Reconsideration which was denied by the Special Master on December 21, 2016. This appeal followed on December 28, 2016.

III. The Special Master's Decision

In his decision, the Special Master focused on the issue of causation.[9] He noted that the experts agreed that the Petitioner suffers from narcolepsy with cataplexy. Where they differ, however, is whether or not FluMist caused the symptoms, specifically the H1N1 strain found in FluMist. Each party submitted multiple expert reports. The Petitioner relied on the reports of Dr. Lawrence Steinman[10], and the Respondents relied upon the reports of both Dr. Michael Kohrman and Dr. Andrew MacGinnitie.

A. Petitioner's Expert: Dr. Steinman

Dr. Steinman opined that the FluMist vaccine interfered with specific receptors responsible for regulating daytime sleepiness resulting in his narcolepsy with cataplexy. Dr. Steinman relied on three expert reports and many medical articles in support of his opinion.

For his causation theory, Dr. Steinman opined that, "components from the wild flu virus contained in FluMist cross-react with certain self-proteins in the brain responsible for sleep regulation, via the mechanism of molecular mimicry."[11] *D'Tiole,* at *10. After this process occurs, Dr. Steinman opined that the body's immune system then attacks the receptors responsible for regulating daytime sleepiness which then caused the narcolepsy in the Petitioner.

---

[9] To receive compensation, a Petitioner must prove either (1) a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to the vaccination in question or, (2) that the illness was actually caused by a vaccine – a Non-Table Injury. *Moberly v. Sec'y of HHS*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) ("[t]o prove causation, a petitioner in a Vaccine Act case must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'"); *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1353 (Fed. Cir. 1999) (proving the vaccine was a substantial factor in bringing about the injury, the petitioner must show, "a medical theory causally connecting the vaccination and the injury."). The Petitioner's claim in this instance is a Non-Table Injury.

[10] Throughout the decision, the Special Master stated that Dr. Steinman is a highly credible expert in this matter, as are Respondent's experts. *See D'Tiole,* at *56 ("I do not dispute Dr. Steinman's qualifications or credibility on these matters.").

[11] Molecular mimicry is defined as a "sequence and/or conformational homology between an exogenous agent (foreign antigen) and self-antigen leading to the development of tissue damage and clinical disease from antibodies and T cells directed initially against the exogenous agent that also react against self-antigen." *D'Tiole,* at *10 n. 9 (citing Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* at 70 (K. Stratton et al., eds. 2011)). *See also Adams v. Sec'y of the HHS*, 76 Fed. Cl. 23, 37 n.23 (2007) ("Molecular mimicry is a phenomenon wherein, two separate peptides or proteins are not identical, but because of the structure or their component of amino acids, in terms of . . . the way they may look to the immune system, they appear to be identical[.]").

Dr. Steinman relied on many studies connecting flu vaccines and narcolepsy. One study Dr. Steinman relied upon, M. Partinen et al., *Increased Incidence and Clinical Picture of Childhood Narcolepsy Following the 2009 H1N1 Pandemic Vaccination Campaign in Finland,* 7 PLoSone3:1-8 at 7 (2012) ("Partinen"), concerned the Pandemrix vaccine, an inactivated form of the flu vaccine containing the H1N1 viral strain also found in FluMist.[12] However, the study concluded that, "there is no other evidence of an increased risk of narcolepsy with any other vaccine than the As03 adjuvanted Pandemrix." Partinen at 7.

Dr. Steinman also submitted two articles that he co-authored explaining why Pandemrix may have caused narcolepsy. *See* S. Ahmed et al., *Narcolepsy, 2009 A(H1N1) Pandemic Influenza, and Pandemic Influenza Vaccinations: What is Known and Unknown About the Neurological Disorder, the Role for Autoimmunity, and Vaccine Adjuvants,* 50 J. of Autoimmunity 1-11 (2014) ("Ahmed I"); S. Ahmed et al., *Antibodies to Influenza Nucleoprotein Cross-React with Human Hypocretin Receptor 2,* 7 Sci. Translational Med. 294 (2015) ("Ahmed II"). Ahmed I proposed that the relationship between narcolepsy and Pandemrix is likely "attributable to how the specific influenza antigen component" was prepared. *D'Tiole,* at *13 (quoting Ahmed I at 1.) Ahmed II suggested that there was a strong correlation between the wild H1N1 virus and narcolepsy. *D'Tiole,* at *18.

In further support, Dr. Steinman relied on F. Han et al., *Narcolepsy Onset is Seasonal and Increased Following the 2009 H1N1 Pandemic in China*, 70 Am. Neurological Ass'n 410 (2011) ("Han"). Dr. Steinman interpreted Han to signify that the wild H1N1 influenza virus itself was correlated to narcolepsy. *D'Tiole,* at *19.

B. Respondent's Experts: Dr. Kohrman and Dr. MacGinnitie

Dr. Kohrman submitted multiple rebuttals regarding Dr. Steinman's reports. Dr. Kohrman first opined that the relevant medical evidence reveals no proof that a live H1N1 type vaccine is associated with narcolepsy. He then opined that due to the Petitioner's poor sleep hygiene it would be too difficult to pinpoint an onset date for the narcolepsy.

In support, Dr. Kohrman first provided that because the FluMist and Pandemrix vaccines are significantly different in their make-up, there is no link between FluMist and narcolepsy. Dr. Kohrman identified that, "FluMist is a non-adjuvanted vaccine, meaning that the adjuvant suggested to cause narcolepsy would not have been present in [the Petitioner's] vaccine." *D'Tiole*, at *26. Dr. Kohrman also relied heavily on the study Duffy et al., *Narcolepsy and Influenza A(H1N1) Pandemic 2009 Vaccination in the United States,* 83 Neurology 1827 (Oct. 15, 2014) ("Duffy")). The study utilized both inactivated and LAIV vaccines. The Duffy authors ultimately concluded that the H1N1 virus strain could not be associated with an increased risk of narcolepsy. *D'Tiole,* at *26.

[12] "A vaccine is rendered inactive through the process of destroying the biological activity of the virus in the vaccine, by the action of heat or other physical or chemical means." *D'Tiole,* at 11 n. 10 (citing *Dorland's* at 925).

Dr. Kohrman also discredited the Han article by showing that it was not a proper epidemiological study of narcolepsy in China, and, therefore, is unreliable.[13] Dr. Kohrman also concluded that the Petitioner's poor sleep habits, and lack of acute symptoms after receiving FluMist, make it difficult to determine when the symptoms occurred. *D'Tiole,* at *24. Dr. MacGinnitie concurred with Dr. Kohrman and explained that given FluMist's distinct formulation, there is no such evidence linking it to narcolepsy. *D'Tioli*, at *30.

Dr. MacGinnitie further explained the production process of each vaccine. He stated that vaccines like Pandemrix are produced by growing the strains in chicken egg cells and then deactivated to kill the virus while leaving the genetic core intact. *D'Tiole*, at *31. LAIV vaccines, such as FluMist, are cold-adapted, and delivered directly into the nose which results in a more limited viral replication "but would also generate antibody titers lower than that of a subunit vaccine like Pandemrix." *D'Tiole,* at *31-32. It is the former antibodies (the higher count of antibodies caused by Pandemrix) that would, under Petitioner's theory via molecular mimicry, inhibit the necessary receptions to cause narcolepsy. As such, Dr. MacGinnitie opined that the theory is limited to vaccines like Pandemrix. He also identified that Duffy observed no cases of narcolepsy out of thousands of patients who received FluMist. *D'Tiole,* at *33. Dr. MacGinnitie also highlighted the correlation between individuals with the HLA allele and narcolepsy and explained in detail how it affects the onset of narcolepsy. *D'Tiole,* at *33-34.

C. The Special Master's Conclusion

Upon reviewing the expert reports and conclusions, the Special Master concluded that Petitioner did not satisfy his burden under *Althen*.[14] The Special Master identified that there were "fundamental holes in the theory," as Petitioner attempted to "leverage a theory that is reliable with respect to one form of the flu vaccine into a case involving a different form, but without showing that the theory is similarly reliable in the different setting." *D'Tiole,* at *55.

The Special Master concluded given the brand of vaccine, components of the vaccine, substantially different manufacturing process, and delayed symptoms of the injury, it was unlikely that Petitioner's onset of narcolepsy was due to his FluMist vaccine and, therefore, did not meet his burden of proof under the *Althen* standard.

IV. Legal Standards

[13] Han's authors acknowledged that the sample of patients in the study were not representative of China as a whole. This concession led Dr. Kohrman to believe, and, therefore, opine that it did not constitute a reliable epidemiological study of narcolepsy in China. *D'Tiole,* at *27-28.

[14] To establish a legal cause in an off-Table case, petitioners must establish each of the three *Althen* factors by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278.

Under the Vaccine Act, a court may set aside a Special Master's findings of fact or conclusions of law only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). With respect to findings of fact, the Special Master has broad discretion to weigh expert evidence and make factual determinations. *See Bradley v. Sec'y of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). The Federal Circuit has clearly indicated its longstanding standard of review when the Court of Federal Claims hears petitions on review from the Special Masters:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted); *see also Snyder v. Sec'y of HHS*, 2014 U.S. App. LEXIS 1674, at *10-11 (Jan. 28, 2014) (quoting *Hodges*).

"If the special master has considered the relevant evidence of the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). This Court ought not to second-guess the Special Master's fact-intensive conclusions, particularly in cases "in which the medical evidence of causation is in dispute." *Hodges*, 9 F.3d at 961. In such cases, which often involve expert testimony, the Federal Circuit has "unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act." *Porter v. Sec'y of HHS*, 663 F.3d 1242, 1250 (Fed. Cir. 2011). "Such credibility determinations are 'virtually unreviewable'" on appeal. *Id.* at 1251. With respect to questions of law, legal rulings are reviewed *de novo* under the "not in accordance with law" standard. *See, e.g.*, *Moberly*, 592 F.3d at, 1321; *Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

V. Discussion

When evaluating a motion for review, as stated above, it is the Court's task to determine whether the Special Master properly considered the relevant evidence in the record, came to a factual conclusion based on plausible inferences, and provided a reasoned explanation in his or her decision. *Hines*, 940 F.2d at 1528. It is not the Court's task to second-guess the Special Master, especially in cases "in which the medical evidence of causation is in dispute." *Hodges*, 9 F.3d at 961. Thus, on review, the Court accords deference to the Special Master's factual findings and fact-based conclusions.

Nevertheless, the majority of Petitioner's memorandum expresses general disagreement with the Special Master's evaluation. Specifically, Petitioner argues three points of error by the Special Master. First, Petitioner alleges that the Special Master "required the petitioner to provide epidemiologic evidence in support of his theory connecting influenza vaccination to narcolepsy" as contrary to *Althen* and *Capizzano v. Sec'y of HHS*, 440 F.3d 1317 (Fed. Cir. 2006). *See* Pet'r's Mem. of Objections at 2. Second, Petitioner contends that "the Special Master required the petitioner to provide proof of a specific biologic mechanism . . . and a logical sequence of cause and effect" demonstrating that the vaccine was the reason for the narcolepsy as contrary to *Knudsen v. Sec'y of HHS*, 35 F.3d 543 (Fed. Cir. 1994). Third, Petitioner argues that the Special Master's decision to "decide the case without a hearing was an abuse of his discretion." *See* Pet'r's Mem. of Objections at 2. In light of the Special Master's detailed and reasoned decision, this Court concludes that these arguments do not provide a basis for this Court to set aside the Special Master's Decision.

A. The Special Master Did Not Require Epidemiological Evidence but Appropriately Considered and Weighed All the Evidence Presented.

Petitioner argues that the Special Master held Petitioner to a higher standard of proof than is required under *Althen* prong 1. Under the first prong, Petitioner is required to prove by a preponderance of the evidence a medical theory causally linking the vaccination and the injury. The Petitioner claims that the unreliability of his theory is based upon the fact that he did not "provide an epidemiological study linking live attenuated influenza vaccines to narcolepsy or a conclusive epidemiological study linking infection with the wild H1N1 virus to narcolepsy." Pet'r's Mem. of Objections at 11.

Respondent concedes that the Special Master used epidemiological evidence in making his decision but maintains that the Special Master "properly considered" the evidence and "found it unpersuasive." Resp't's Mem. in Response to Pet'r's Mot. for Review at 9.

The Federal Circuit held in *Althen* and *Capizzano* that "*requiring* epidemiologic studies . . . impermissibly raises a claimant's burden under the Vaccine Act." *Capizzano*, 440 F.3d at 1325 (emphasis added). *See also Cedillo v. HHS*, No. 98-916V, 2009 WL 331968, at *92 (Fed. Cl. Feb. 12, 2009) ("it would [not] be proper for a special master to base a *causation* ruling *entirely* on epidemiologic evidence; the special master must consider *all* the evidence of the record, including opinion evidence, circumstantial evidence, etc."). Even though the molecular mimicry theory proffered in this case can be a "plausible component of a causation theory," under *Althen* prong 1, it is not "always viewed as a plausible theory in every case." *R.V. v. Sec'y of HHS*, No. 08-504V, 2016 U.S. Claims LEXIS 935, at *146 n.91 (Fed. Cl. Feb. 19, 2016).

Upon reviewing the decision, this Court holds that the Special Master did not require Petitioner to present epidemiological evidence to establish a causal relationship. But rather the Special Master's language indicates that Petitioner failed to establish causation altogether, thus failing the first prong under *Althen.* The Special Master notes, that the evidence presented by Petitioner considers a completely separate form of the influenza vaccine.

> At present, however, Dr. Steinman's own research suggests that the theory he proposes applies only to a form of the flu vaccine not at issue in this case. It therefore lacks sufficient reliability in this context to carry Petitioner's *Althen* prong one burden.

D'Tiole, at *68.

Moreover, the use of epidemiological evidence can be weighed by the Special Master under some circumstances. In *Lampe v. Sec'y of HHS*, 219 F.3d 1357, 1365 (Fed. Cir. 2000), the Federal Circuit held that, "[a]n epidemiological study may be probative medical evidence relevant to a causation determination." *See also Cedillo*, 2009 WL 331968, at *92 (noting that when "a general causation issue has been the subject of epidemiological studies . . . it is quite appropriate for the special master to consider such epidemiological evidence, and to give that evidence appropriate weight under the circumstances," along with all other evidence).

The Special Master properly weighed the evidence, including the epidemiological studies and assigned each its proper weight. The Special Master wrote,

> Petitioner's theory could well become more reliable once there is stronger proof linking the LAIV form of the H1N1 flu vaccine, or better and more consistent evidence linking the H1N1 wild virus alone, to narcolepsy.

D'Tiole, at *67. This sentence does not indicate that the Special Master required Petitioner to offer epidemiological evidence, but rather the evidence Petitioner did put forth is unpersuasive.[15]

Moreover, the Special Master identified specific elements of the Petitioner's reports that undercut his own argument. He identifies that both,

> Ahmed I and II thus stand for the proposition that something about the process of inactivating the viral strain in manufacturing that form of the flu vaccine is associated with increasing the number of nucleotide antibodies — not that the mere presence of H1N1 proteins in any form, and in any version of the flu vaccine, will inevitably result in sufficient levels of the antibodies to produce the same cross-reactive autoimmune process . . . This case, by contrast, involves a different form of the vaccine, subject to a wholly different manufacturing process in which the flu strain is live but attenuated. Other than also being an H1N1 strain, Petitioner has not shown why, or how, the LAIV version would be comparable to Pandemrix . . . in increasing the nucleoprotein antibodies.

[15] The Special Master acknowledges that the Petitioner potentially put epidemiological evidence into contention. However, "where a petitioner relies on such evidence to suggest a vaccine likely could cause a particular disease or condition, then he must also persuasively explain or rebut contrary evidence — he cannot simply take refuge behind the general proposition that Vaccine Act claimants need not usually offer such evidence." *D'Tiole*, at 67 n. 23.

D'Tiole, at 58-59. The Special Master also indicated that the Respondent's experts persuasively demonstrated that the H1N1 strain used to manufacture FluMist is too different from the form studied in Ahmed II. *D'Tiole*, at 59 n. 20. He later concludes that, "Petitioner attempted to close such gaps in his causation theory, but failed to do so persuasively, with his arguments consistently rebutted by evidence Respondent offered." *D'Tiole*, at 60-61.

Under *Lampe* and *Cedillo*, the Special Master has clear authority to weigh all the evidence, including epidemiological evidence probative to a relevant causation determination. The decision makes clear that the Special Master thoroughly and properly evaluated the evidence of record and made his determination (that Petitioner failed to prove causation), in a reasonable manner. As this court ought not to second-guess the Special Master's fact-intensive conclusions, particularly in cases "in which the medical evidence of causation is in dispute," *Hodges*, 9 F.3d at 961, the Court will not do so here. The Federal Circuit has "unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act." *Porter*, 663 F.3d at 1250. Therefore, the Special Master's conclusion that Respondent's experts were more persuasive than Dr. Steinman was not improper.

B. The Special Master Did Not Require Proof of a Specific Biologic Mechanism

Petitioner maintains that the Special Master required proof of a specific biologic mechanism demonstrating causation in violation of *Knudsen*. The Federal Court stated in *Knudsen*, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." *Knudsen*, 35 F.3d at 549. Or in other words, there is "no objective confirmation requirement in the Vaccine Act's preponderant evidence standard." *Althen*, 418 F.3d at 1279. The Federal Circuit continued in explaining that given the legislative intent of the Vaccine Act, the purpose was to establish a "fair [and] simple" compensation program where "awards are to be 'made to vaccine-injured persons quickly [and] easily.'" H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 18, *reprinted in* 1986 U.S.C.C.A.N. at 6344, 6348.

Petitioner points to the Special Master's unwillingness to extend the epidemiological study theories concerning Pandemrix to FluMist. Pet'r's Mem. of Objections at 14. Petitioner relies on the Special Master's language that, "[s]tudies measuring the nucleoprotein antibody levels in individuals vaccinated with FluMist would also be useful in supporting the theory." *D'Tiole*, at *67. Petitioner continues to argue that in the context in which this sentence was written, the Special Master required the Petitioner to prove the specific biologic mechanism he put forth. The Petitioner also claims that the Special Master's observation in a footnote that, "there is no evidence that Petitioner had any of the H1N1-derived nucleoprotein antibodies that would theoretically interact with his hypocretin production," directly undermines the purpose of the Vaccine Act. *D'Tiole*, at *69 n. 24. For "it is usually impossible to provide such evidence" of a specific biologic mechanism. Pet'r's Mem. of Objections at 16.

Regarding the lack of evidence regarding the nucleoprotein antibodies, in the next sentence of the footnote, the Special Master acknowledges that this omission "does not deserve any significant weight." *D'Tiole*, at *69 n. 24. The Special Master concluded that:

> It is simply too great of a leap for me to conclude that, because one form of the flu vaccine may plausibly cause narcolepsy due to manufacturing differences that promote an excess of certain antigens that could theoretically provoke an autoimmune reaction, a significantly different form of the vaccine would necessarily have the same effect in the United States — especially given reliable epidemiologic evidence to the contrary, as well as admissions found in Petitioner's own scientific evidence.

D'Tiole, at *68-69.

Even though it is inappropriate to require a Petitioner to prove a specific biologic mechanism under *Althen*, a claimant still must prove "a medical theory causally connecting the vaccination and the injury," by the preponderant standard. *Althen*, 418 F.3d at 1278 (citing *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Special Master did not require proof of a specific biologic mechanism, but rather that the petitioner's own evidence suggested that his theory of causation did not apply to the vaccine he received.

Further, the Special Master noted that because the molecular mimicry theory is short in establishing a logical causal connection between the vaccine and narcolepsy, the only evidence remaining are the comments made by the Petitioner's mother in February 2012. The Special Master was not convinced that "some" narcolepsy symptoms experienced in February 2012 and then additional symptoms appearing "several months later" constituted a "coherent, logical sequence of cause and effect," (*Althen* prong 2) that related back to his December 2011 vaccination. *D'Tiole,* at *70-71.

Moreover, the Special Master held that the Petitioner did not establish the third *Althen* prong of timeliness.

> Petitioner has not adequately demonstrated that the proposed timeframe in which he would be expected to experience the autoimmune process interfering with his hypocretin production, and resulting in narcolepsy, was medically reasonable . . . [T]he medical records are inconsistent on the scope or progression of these symptoms in the ten months after [Petitioner] received the vaccine. Thus, although there is evidence of onset in the late winter of 2012, the records from Petitioner's neurologic and epilepsy consult in October 2012 make little mention of sleep problems as Petitioner's primary concern, and do not themselves corroborate the earlier records. And . . . there is zero record evidence that evinces the existence of an autoimmune process occurring in the seven months after vaccine administration. It is therefore impossible to conclude that the [Petitioner's] proposed timeframe actually played out as would be expected.

D'Tiole, at 70-71.

Given the extreme deference Congress authorized for the Special Masters when drafting the Vaccine Act, it is this Court's opinion that the Special Master's reasoning was not arbitrary

or capricious, or otherwise not in accordance with law. As explained above, the Special Master concluded that the Petitioner failed to meet his requirement under *Althen*, and, after reviewing the Special Master's reasoning, this Court will not second guess his opinion.

C. The Special Master was Within His Authority to Issue a Decision Without a Hearing and thus was Not an Abuse of Discretion

Petitioner's final argument revolves around the Special Master's decision to issue an order on the written record without a hearing. Petitioner argues that under the circumstances of his case, he was not offered a "full and fair opportunity to present" his case citing Vaccine Rule 3(b) of the RCFC. However, Petitioner concedes that under the Vaccine rules, a Special Master may issue a decision without a hearing. *See* RCFC, App. B, Vaccine Rule 8(d) ("The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing."). *See also* 42 U.S.C. § 300aa-12(d)(3)(B)(iii)(v) ("[i]n conducting a proceeding on a petition a special master . . . may require the testimony of any person and the production of any documents as may be reasonable and necessary . . . [and] may conduct such hearings as may be reasonable and necessary."). Both the statute as well as the rule use the discretionary word "may." In essence, the decision to hold a hearing falls within the complete discretion of the Special Master.

Here, however, Petitioner argues that the decisions issued without a hearing are either cases in which: (1) the parties agreed, (2) "claims in which the petitioner is relitigating a medical theory" that was not persuasive in former cases, and (3) "claims in which the petitioner's written submissions present a very weak case." Pet'r's Mem. of Objections at 17. Further, Petitioner maintains that a hearing should have been given, *inter alia*, because, Petitioner is relying on a new medical theory that could not have been explained thoroughly via written submissions. Because of this, Petitioner argues that Dr. Steinman deserved an opportunity to explain why his medical theory extended from Pandemrix to FluMist.

However, even though this is the first application of Dr. Steinman's theory of Pandemrix to FluMist, the theory of molecular mimicry is not new to the Special Masters. *W.C. v. Sec'y of HHS*, 704 F.3d 1352, 1360 (Fed. Cir. 2013) (attempting to establish the link between Multiple Sclerosis and an influenza virus via molecular mimicry), *Hennessey v. Sec'y of HHS*, 91 Fed. Cl. 126, 134-35 (2010) (expert's overly broad application of the molecular mimicry theory made it meaningless).

The Special Master concluded that holding an evidentiary hearing was not needed because "whether research involving Pandemrix applies to FluMist – is self-evident from their reports." *D'Tiole*, at *79. As such, there was no need to pose questions that uncovered new enlightening information non-existent from the filings. This is especially important, considering the Special Master explicitly limited his decision to the persuasiveness of the arguments. *See D'Tiole*, at 60-61 ("[p]etitioner attempted to close such gaps in his causation theory, but failed to do so persuasively, with his arguments consistently rebutted by evidence Respondent offered.").

The Special Master acknowledged the numerous exhibits and reports submitted by Petitioner over a year's span in which Petitioner could have made a sufficient showing how the

Pandemrix theory extends to FluMist. He further noted, "[t]he experts had ample opportunity to review each other's opinions and respond accordingly, in keeping with the 'full and fair opportunity' duty that informs whether to hold a hearing." *D'Tiole,* at *79. The Special Master has the most discretion in deciding when to rule, and given that he is well acquainted with the ebb and flow of the litigation, the Court is not in a position to second guess his decision.

As the Special Master identified, "a hearing usually provides a petitioner with the opportunity to put on live testimony which aids the special master most in cases where witness credibility is at issue, or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings." *D'Tiole*, at *72. *See Murphy v. HHS*, No. 90-882V, 1991 WL 71500, at *2 (Cl. Ct. Spec. Mstr. Apr. 19, 1991) (a hearing is not necessary where the positions of the parties are fully developed and the special master does not need to weigh the credibility of the witnesses). In fact, multiple times throughout the decision, the Special Master acknowledged the "competency [and] expertise" of Dr. Steinman. *D'Tiole*, at *73 n. 27.

In addition to not holding a hearing, Petitioner also alleged in the Motion for Reconsideration, that the Special Master abused his discretion when he did not take into consideration an article referenced as an authority in Ahmed II before drafting his November decision.[16] J. Montplaisir et al., *Risk of Narcolepsy Associated with Inactivated Adjuvanted (AS03) A/H1N1 (2009) Pandemic Influenza Vaccine in Quebec*, 9 PLOSone 9:1-9. This study demonstrated an increased incidence of narcolepsy associated with another version of the inactivated H1N1 pandemic vaccine, Arepanrix. *D'Tiole v. Sec'y of HHS,* No. 15-085V, 2016 U.S. Claims LEXIS 2092, at *10 (Fed. Cl. Dec. 21, 2016). However, as the Special Master indicated, he has since reviewed it, and decided it does not provide grounds for reconsideration of the case:

> My reasoning runs parallel to the authors of Ahmed II, who themselves found that not all forms of vaccines more akin to Pandemrix than FluMist were similarly

[16] This particular article was listed among 80 authorities in Ahmed II and was not offered by itself as evidence before the issuance of the Special Master's decision. Petitioner further maintains that the Special Master failed to acknowledge in his decision to deny reconsideration a letter to the editor focusing on narcolepsy centers in the United States, France, and Canada. *D'Tiole,* 2016 U.S. Claims LEXIS 2092, at *8 (discussing Dauvilliers et al., *Letter to the Editor: Post H1N1 Narcolepsy-Cataplexy*, 33 SLEEP 11:1428-1430). The Special Master did not discuss this article for it was a letter to the editor lacking reliable scientific variables, cited first by the Respondent, and "limited" in scientific usefulness. *D'Tiole,* 2016 U.S. Claims LEXIS 2092, at *8 (identifying that the Dauvillers article, "creat[es] difficulty in making a specific association between narcolepsy onset and H1N1 infection as opposed to vaccination."). Because it is not an error to "disregard [a] piece of scientific literature not raised as significant by petitioner," the Special Master did not err by omitting it from his order. *D'Tiole*, 2016 U.S. Claims LEXIS 2092, at *10 (citing *Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1347 (Fed. Cir. 2010)).

> associated with narcolepsy . . . It does not stand as a newly-discovered, let alone critical, evidentiary basis for reconsideration.

D'Tiole, 2016 U.S. Claims LEXIS 2092, at *11-12.

Even though the Petitioner claims that this is a case of first impression, this fact does not change this Court's opinion that the Special Master did not abuse his discretion. As the Special Master correctly identified, "the standard is whether Petitioner has had a fair chance to present his case." *D'Tiole*, 2016 U.S. Claims LEXIS 2003, at *79. In this case the Special Master observed that "the experts all had ample opportunity to review each other's opinions," and a decision could have been made on the papers. *D'Tiole*, at *37. *See also Veryzer v. Sec'y of HHS*, 98 Fed. Cl. 214, 225 (2011) ("[i]n this case the special master observed that 'both parties have expressed themselves fully herein, as certainly as [the witness] did in his lengthy report, (citations omitted), and, after a detailed opinion that thoroughly analyzed the opinions and credentials of both experts, he deemed the evidence to be so 'patently unreliable' that a hearing would be a waste of time and resources (citations omitted).").

The Court holds that the Special Master did not abuse his discretion by issuing a decision on the written record.

VI. Conclusion

For the reasons stated above, the Court **DENIES** Petitioner's motion for review and **SUSTAINS** the decision of the Special Master. The clerk is directed to enter the judgment accordingly.

IT IS SO ORDERED.

/s/ Edward J Damich
EDWARD J. DAMICH
Senior Judge